

WALSH
PIZZI
O'REILLY
FALANGA

THREE GATEWAY CENTER
100 Mulberry Street, 15th Floor
Newark, NJ 07102
T: 973.757.1100
F: 973.757.1090
WALSH.LAW

Liza M. Walsh
Direct Dial: (973) 757-1101
lwalsh@walsh.law

November 1, 2022

VIA ELECTRONIC FILING

Honorable Madeline Cox Arleo, U.S.D.J.
U.S. District Court for the District of New Jersey
Martin Luther King Jr. Building & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *Alkermes, Inc. v. Teva Pharmaceuticals USA, Inc., et al.*
Civil Action No.: 2:20-cv-12470 (MCA/MAH)

Dear Judge Arleo:

This firm, together with Sterne, Kessler, Goldstein & Fox P.L.L.C., represents Defendant Teva Pharmaceuticals USA, Inc. ("Teva") in connection with the above-referenced matter. We write, together with counsel for Alkermes, in advance of the November 9, 2022 hearing on the Motions *in limine* to obtain the Court's guidance on certain issues and agreements relating to the upcoming trial that were discussed during the final pretrial conference and thereafter. In addition, the parties seek to memorialize guidance they have already received from Your Honor's chambers concerning the upcoming trial.

First, the parties understand that the Court scheduled a hearing on the pending Motions *in limine* on November 9, 2022 at 2:00 pm in Newark – Courtroom 4A. D.I. 180. The pending Motions *in limine* are listed below:

1. Teva's Motion *in limine* to preclude Alkermes from providing evidence or testimony, or otherwise referencing, Teva's purported role in the "opioid crisis." D.I. Nos. 161, 162, 174, and 176.
2. Teva's Motion *in limine* to preclude Alkermes from providing evidence or testimony, or otherwise referencing, Teva's decision or rationale to file its ANDA. D.I. Nos. 163, 164, 175, and 176.

Second, as directed by Judge Hammer, the parties will be prepared to discuss during the upcoming hearing the parties' plans regarding witnesses who will be testifying live versus through deposition designation. The parties also await the Court's direction on how the Court would like to receive any deposition designations.

Third, it is the parties' understanding that the trial will be conducted in-person on November 14-17, and 21-22, 2022. It is also the parties' understanding that the trial day will run

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from approximately 9:30 a.m. to 4:30 p.m., with two 15-minute breaks (one in the morning and one in the afternoon), and a half-hour lunch.

Fourth, the parties have conferred and, subject to Your Honor's approval, have reached agreement to present opening statements for not more than 1 hour, 15 minutes each. As set forth in the Final Pretrial Order (D.I. 165 at 220), Teva will present its opening statement concerning its defenses of patent invalidity first, followed by Alkermes' responsive opening statement with respect to patent validity.

Fifth, the parties have reached a compromise regarding their dispute over the order of presentation set forth in the Final Pretrial Order (D.I. 165 at 220). Specifically, the parties agree that Teva will present its case on its defenses of patent invalidity first, including objective indicia/secondary considerations of non-obviousness, except for testimony and evidence regarding the economic aspects of commercial success. Alkermes will then present its case on patent validity in response, including its case on objective indicia/secondary considerations of non-obviousness. Finally, Teva will then present its reply case regarding the economic aspects of commercial success. Teva agrees it will call each of its witnesses only once unless permissible in accordance with applicable authority governing reply evidence to rebut previously undisclosed evidence or arguments Alkermes presents at trial; Alkermes may object to such reply evidence to the extent it believes such testimony should have been presented in Teva's case-in-chief.

Sixth, the parties agree that, based on the parties' pretrial exchanges and for the purposes of this trial, the invention date for the asserted claims of the '499 patent is April 22, 2004, which is the date of the first patent application filing, and Alkermes will not seek to prove an earlier date of invention.

Seventh, pursuant to the conversation with Your Honor's staff, it is the parties' understanding that trial exhibits shall be submitted to Your Honor on two thumb drives before the start of trial. The parties will also submit one thumb drive to the Court Reporter. It is also the parties understanding that two copies of any daily witness binders shall be prepared and submitted to Your Honor, and an additional copy of all daily witness binders will be provided to the Court Reporter.

Eighth, it is the parties' understanding that Your Honor would prefer to have expert reports submitted via email. The parties await the Court's direction regarding the deadline for the submission of the expert reports. The parties also seek clarification regarding whether the Court wishes to receive copies of the documents cited by the experts in the reports at this time, which are voluminous, in addition to the reports themselves.

Finally, the parties understand that they will be given access to the courtroom on November 10, 2022, to set up the courtroom for trial and to bring in any supplies required for trial. The parties are in the process of conferring regarding the technology for the courtroom set up for trial and will be submitting a separate letter for Your Honor's approval regarding the technology set-up and permission to bring any necessary equipment and materials into the courthouse.

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We thank the Court for its consideration of this submission and ongoing attention to this matter and remain available should Your Honor or Your Honor's staff have any questions.

Respectfully submitted,

/s/ Charles M. Lizza

Charles M. Lizza

Counsel for Alkermes

Respectfully submitted,

/s/ Liza M. Walsh

Liza M. Walsh

Counsel for Teva

cc: All Counsel of Record (via ECF and email)

SO ORDERED.

Hon. Madeline Cox Arleo, U.S.D.J.